SUBCOMMITTEE NO. 3 Agenda
Health, Human Services, Labor & Veteran's Affairs

Chair, Senator Denise Ducheny

Senator Wesley Chesbro
Senator Dave Cox

March 13, 2006

10:00 AM

Room 4203
(John L. Burton Hearing Room)

(Diane Van Maren)

Item	**Department**
4260	**Department of Health Services—*Selected Issues as Noted***

PLEASE NOTE: Only those items contained in this agenda will be discussed at this hearing. *Please* see the Senate File for dates and times of subsequent hearings.

Issues will be discussed in the order as noted in the Agenda unless otherwise directed by the Chair. Thank you.

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A. ITEMS FOR "VOTE ONLY" (One Item)

1. Botulism Immune Globulin (BabyBIG)—Change in Manufacturing Facility

Issue. The DHS **proposes an increase of $1.1 million (Infant Botulism Treatment and Prevention Fund) *one-time only* to support an unavoidable change in one of the manufacturing facilities and to meet U.S. Food and Drug Administration (FDA) requirements.**

According to the DHS, the present manufacturer, who is specified in the FDA license as the plasma fractionators, will no longer be part of the manufacturing process of BabyBIG. The DHS must find a replacement in order to continue producing and supplying the medicine. Any technical transfer of proprietary methodology and technology requires an amendment to the license. Any license changes automatically require extensive studies of proof of capability in the new facility (per FDA). According to the DHS, these studies will cost $1.1 million in 2006-07. The next production of BabyBIG will be in 2008-09.

Background—Status of General Fund Loan. At one time BabyBIG had $2.9 million in outstanding General Fund loans. According to the DHS, the General Fund loan balance is now about $375,000 and will be paid in full in 2006-07.

Background—Description of the Program: Infant botulism occurs when the botulism bacteria temporarily colonizes and produces toxin in the baby's intestine. It is the most common form of human botulism in the United States. About 100 cases occur in the U.S. each year, with about 30 to 50 percent of these occurring in California.

BabyBIG is the DHS-sponsored Orphan Drug that treats infant botulism by neutralizing botulinum toxin. It is the only antidote available in the world for this purpose. In October 2003 the federal FDA issued a license to the DHS to manufacture and sell BabyBIG. The manufacturing process of the treatment takes about one year.

Prior to licensure, the DHS had been selling the drug to hospitals at a pre-license charge of $1,560. However through statutory effective July 1, 2004, the unit dosage now is purchased by hospitals at a cost of $45,300. **This change has enabled the program to recover development costs and to become more self-sustaining (i.e., not reliant on state General Fund support, but fee supported revenues).**

Treatment with BabyBIG has reduced average hospital stay from 5.7 weeks to 2.3 weeks and reduced average hospitals costs from $163,400 to $62,500, a savings of about $100,000 per case (using 2004 dollars). **As such, third-party insurers and hospitals like to use BabyBIG because of the reduction in complications and cost-savings that it provides. Treatment of these patients with BabyBIG saves the Medi-Cal Program more than $1 million annually.**

Subcommittee Staff Recommendation. It is recommended to approve as proposed.

B. ITEMS FOR DISCUSSION *(Individual issues begin on page 6)*

Overview of Public Health Emergencies. The Governor's Office of Emergency Services (OES) is the lead emergency management agency in California. It coordinates the state's response to major emergencies in support of local jurisdictions, which have the primary responsibility for responding to the effects of an emergency. **Local governments generally are expected to be the first responders to a disaster using local resources.**

The OES has prepared the **"State of California Emergency Plan"** which establishes a system for coordinating all phases of emergency management in California. These phases include:

- *Preparedness:* These are activities undertaken in advance to ensure readiness for responding to an emergency, such as developing emergency plans and mutual aid operational plans, training staff, and conducting exercises to test plans and training.
- *Response:* These are activities undertaken to respond to an emergency, such as activating warning systems and mobilizing resources. Emphasis is placed on saving lives, controlling the situation, and minimizing the consequences of a disaster.
- *Recovery:* These activities are undertaken to return to pre-disaster conditions, such as replacing pharmaceutical supplies.
- *Mitigation:* These activities are undertaken to eliminate or reduce the impact of future disasters

As part of the state emergency plan, the OES developed the **"Standardized Emergency Management System (SEMS)"** which is the state's overall framework for managing multi-agency and multi-jurisdictional emergencies in California. **SEMS consists of five organizational levels (i.e., Field, Local, Operational Area, Regional and State) which are activated as needed to respond to emergencies, including those caused by infectious disease agents.**

SEMS uses the "incident command system" which provides a means to coordinate the efforts of individual agencies as they work toward stabilizing the incident and protecting life, property, and the environment. State law requires state agencies to use SEMS, and local jurisdictions must use SEMS to be eligible for reimbursement of response-related personnel costs under disaster assistance programs.

The Department of Health Services (DHS) is the lead state agency for responding to public health emergencies such as infectious disease emergencies. The role of the DHS includes: (1) coordinating the state's overall preparedness and response effort, **(2)** providing policy direction, technical expertise and consultation, **(3)** maintaining expert laboratory resources, **(4)** receiving information about health threats and directing them to the appropriate program or local health jurisdiction, **(5)** facilitating public health alerts, and notification, and **(6)** providing direct response when an event exceeds local capacity.

Local health jurisdictions (61 through out the state) are the point of delivery for public health services and in emergencies provide response *within their capability*. Each jurisdiction has a local health officer (a physician) who is statutorily invested with authority to take necessary actions within its jurisdiction to control the spread of disease or occurrence of additional cases. These actions can range from ordering and enforcing isolation and quarantine of individuals to seizure and destruction of property and restricting school attendance by teachers and students.

State regulations require that local health jurisdictions serving populations of 50,000 or more to provide laboratory services from an approved public health laboratory. California has 38 public health laboratories. A local jurisdiction without its own laboratory can contract with another jurisdiction or use one of the state laboratories to meet its requirement.

During infectious disease emergencies, local and state health laboratories provide testing services to identify the presence of infectious agents, support investigations of disease outbreaks, and aid in efforts to control the spread of disease. When a bioterrorism event is suspected, designated laboratories perform more complex specimen testing services that require special laboratory protocols (such as for anthrax, smallpox, West Nile Virus and many others). The federal government—usually the Centers for Disease Control (CDC)—can also provide assistance in emergencies and under specified circumstances.

Planning for natural disasters, terrorism, or infectious disease outbreaks requires preparation by both the state and local health jurisdictions.

Overall Background—Federal Funding of Homeland Security and Bioterrorism.
California receives over $300 million (federal funds) in homeland security and bioterrorism funds**.** These funds are intended to improve the state's emergency preparedness and response in case of a disaster. Though there are federal requirements, as well as certain federal restrictions, the state does have some flexibility on how funds are used each year. In addition, many department's baseline budgets include funding for emergency planning, training, and response activities.

The Department of Health Services (DHS) administers two bioterrorism grant programs. The grant from the federal Centers for Disease Control (CDC) provides grant funds to address threats that impact the public health of our communities. The grant from the federal Health Resources and Services Administration (HRSA) provides funds for hospitals, clinics, and emergency services administrations to support preparedness for response.

With respect to the grant funds from the federal CDC, about 70 percent of these funds are provided to Local Health Jurisdictions (61 entities) and 30 percent is expended by the DHS. The DHS presently funds about 95 positions with the federal CDC grant.

The DHS hand outs provide more detailed information on these funds and expenditures.

Governor's Proposed Augmentations for Public Health Emergency Preparedness. The budget proposes a total increase of **(1)** $11.7 million (General Fund) and 7.1 personnel years for the current year, and **(2) $47.6 million (General Fund) and 60 positions for the budget year for the DHS to expand its response and preparedness for public health emergencies, including pandemic influenza.**

The budget year proposals are discussed below. The current-year proposals will need to be address in legislation.

Availability of Additional Federal Funds—20 Percent is Accessible. After the Governor's budget was released, the federal government **awarded California a total of $9.6 million** ($6.7 million to the DHS and $2.9 million to Los Angeles County**) for state and local response capacity, particularly for the planning and implementation of pandemic influenza response plans and related activities. At this time, it appears that these funds are one-time only. Future appropriations would require Congressional action.**

According to the DHS, the federal CDC has authorized California to be able spend up to 20 percent of the grant (i.e., about $1.3 million). The remaining 80 percent is presently restricted until federal guidance is provided. The DHS has stated that a small portion of the 20 percent in funds needs to be used for a statewide conference in which the federal government will participate. However the remaining amount has not yet been designated since *formal* federal guidance is still forthcoming.

Further, an additional $250 million (federal funds) is to be allocated nationally in the future. Though it is unknown at this time what level of funding California will receive and how much may be specifically available for public health purposes.

1. Local Health Department Preparedness for Pandemic Influenza

Issue: An increase of **$17.9 million (General Fund)** is proposed to develop and implement pandemic influenza plans at the local level and to provide state support in these efforts. **Of this total amount, $1.9 million is for state support and $16 million is for local assistance.**

Specifically, this proposal consists of the following components:

- *Local Health Department Allocation ($16 million).* A total of **$16 million** (General Fund) is proposed for allocation to local health jurisdictions (all 61 in the state). **It is the intent of the Administration to provide this level of funding for *two-years* (i.e., 2006-07 and 2007-08) in order to strengthen and maintain local ability to respond to a pandemic influenza.**

  According to the DHS, each local health jurisdiction will receive a minimum base funding amount of $100,000 for a total expenditure of $6.1 million. The remaining $10 million would then be allocated based on county population. (This method of allocation has historically been used for several grants.)

  The DHS states that these funds would be used to address *locally identified* needs such as the following:

  - Increasing epidemiology and surveillance levels;
  - Improving risk communication;
  - Conducting more laboratory testing;
  - Training local government staff to conduct certain activities;
  - Conducting exercise plans and establishing protocols in all areas;
  - Planning and coordinating health care surge capacity, including alternate care sites;
  - Developing strategies for non-medical case management; and
  - Planning allocation and prioritization strategies for antivirals and vaccines.

- *State Support Funds ($1.9 million).* The DHS is also requesting **$1.9 million** for state support functions as follows:

  - **$500,000 is to support five new positions**—three Health Program Specialist I's, and two Associate Governmental Program Analysts (two-year limited term). The three Health Program Specialist I's would be used to provide technical assistance to the local health jurisdictions. Technical assistance would be provided on-site at the local level and through coordination of consultation across the DHS.

    One Associate Governmental Program Analyst (AGPA) position would serve as a project coordinator for implementing the training program. The other AGPA would manage the local assistance funds at the state level, including

making allocations to the local health jurisdictions and monitoring expenditures.

- **$1.4 million is for consultant contracts.** Of this amount, $1 million is for regional and local training, and the remaining $400,000 is for other as yet undefined activities.

  The DHS states that training will cover topics such as distribution and dispensing of antivirals and vaccine, isolation and quarantine, use of personal protective equipment, developing surge capacity, mental health crisis management, community engagement and education.

Legislative Analyst's Office Recommendation—Deny the Proposal. The LAO recommends deleting the entire $17.9 million (General Fund) proposal. The LAO contends that some of the DHS' proposals for emergency preparedness, including this one, appear to fall within the parameters of the federal bioterrorism funding.

Subcommittee Staff Recommendation. It is **recommended to modify the DHS request** to provide for the following components:

- *Local Health Jurisdiction Funding (Approve)*. It is recommended to provide the $16 million General Fund appropriation as requested. Though federal bioterrorism funds have been provided to local health jurisdictions, many recent reports continue to express concerns regarding the need to build infrastructure. Specifically the Rand Corporation Report (August 2004), the series of hearings and reports prepared by the Little Hoover Commission, and the Bureau of State Audits Report (August 2005) all note the need for increased local health jurisdiction infrastructure, including the need for scientific and surveillance expertise.

- *State Support (Modify).* It is recommended to fund the three Health Program Specialist I's but to delete the two Associate Governmental Program Analysts (AGPA's). The three Health Program Specialist I's would provide assistance to the 61 local health jurisdictions as specified to ensure that each area completes their plans and has tangible operational goals. Deletion of the two AGPA's would result in savings of $180,000 (General Fund). Monitoring of the training and any accounting functions can be performed by existing state staff funded using the federal bioterrorism funds.

Questions. The Subcommittee has requested the DHS and LAO to respond to the following questions.

1. DHS, Please briefly describe the proposal and the need for funding.

2. DHS, How does this proposal interact with existing activities presently conducted using the federal bioterrorism funds.

3. LAO, Please present your concerns.

2. Managing Antivirals for Pandemic Influenza

Issue. The budget contains **an increase of $1.5 million (General Fund) of which $200,000 is for state support and $1.3 million is for local assistance.** The DHS plans to use antivirals (such as Tamiflu) to strategically contain small disease clusters of pandemic influenza and thus potentially slow the spread of any outbreak of the virus, particularly until a vaccine is available.

Specifically, the $1.5 million (General Fund) would be expended as follows:

- *Local Assistance ($1.3 million).* **This appropriation would be used to purchase about 200,000 doses of antiviral** (such as Tamiflu or the most effective product known at the time)**.** This dosage amount would provide 20,000 5-day treatment courses, or 10,000 or less prophylaxis or preventative courses (i.e., 10 days to 8 weeks, depending on length of treatment needed) in the event that the virus is not contained quickly.

- *State Support ($200,000).* This **appropriation would be used to fund one Associate Governmental Program Analyst (AGPA) position *and* to provide $111,000 for consultant services.** The AGPA position is to be used to manage the antiviral, vaccines and medical supplies that California would need during a pandemic. **This would include activities such as (1)** determining gaps in available inventories of antivirals, vaccine and medical supplies, **(2)** provide ongoing monitoring of developed medical and drug supply inventories, and **(3)** monitor expiration dates of the antiviral in the state-owned cache and work with vendors to rotate as much as possible.

  With respect to consultant services, the DHS intends to enter into an interagency agreement with a University of California campus. The funds would be used for the following:

  - Develop methodology including inventory instrument, for conducting initial and quarterly surveys of inventory of state-wide antiviral, vaccine, medical and pharmaceutical caches (384 caches throughout the state) plus vendor inventories (28 major drug wholesalers and medical supply distributors) for pandemic-related drugs.
  - Establish agreements with private entities for medical and drug inventories for both pandemic and general emergency preparedness. (These agreements would be managed by the AGPA on an ongoing basis.)

Background—Role of DHS in Managing Antivirals & Vaccines. The DHS is the lead state agency responsible for managing federal pharmaceuticals and medical supplies that California may receive during a large-scale disaster or emergency.

The federal Pandemic Influenza Plan recommends that state health departments obtain and stockpile antivirals and vaccines, track supply and administration, and

distribute material to the local level. The DHS notes that managing a large volume of doses potentially numbering in the millions will require the development of a strong program operating under careful management.

The DHS also notes that the statewide inventory of emergency pharmaceuticals and medical supplies is not accurately known at this time and there is no system in place to rapidly determine available material or procure needed material. The proposed AGPA position and consultant services with provide assistance with this as well.

Legislative Analyst's Office—Approve. The LAO recommends approval of this proposal.

Subcommittee Staff Recommendation. It is **recommended to approve the $1.5 million (General Fund) as proposed.** The proposal is consistent with federal requirements and would facilitate California to initiate rapid treatment and prophylaxis when the first case appears in the state. In the event a pandemic does occur, the DHS states that this stockpile would supplement the limited federal supply.

Questions. The Subcommittee has requested the DHS to respond to the following questions.

1. **DHS**, Please provide a brief summary of the budget proposal.

3. Infectious Disease Laboratory Infrastructure—Strengthen Surge Capacity

Issue. An **increase of $4.2 million (General Fund) is proposed to provide $1.7 million for state support to fund 13 new positions and $2.5 million for local assistance. This request includes funds to implement new tests to control both old and new infectious disease, and to establish pre-doctoral and post-doctoral training programs to provide a qualified pool of candidates to replace local laboratory directors as they retire.**

Specifically the $4.2 million (General Fund) would be expended as follows:

- *Local Assistance ($2.5 million).* There are **38 Public Health Laboratories** (operated by local health jurisdictions) in California which are an integral component to the state's response system to mitigate communicable and infectious disease outbreaks, detect bioterrorism, detect exposure to chemical toxins, and other public health-related concerns and emergencies.

  The Public Health Laboratory directors, as well as the Little Hoover Commission (2003 report on public health system), have identified significant concerns related to maintaining and expanding California's public health system. **A key component is the ability to recruit and retain a clinical workforce.**

  Many of the directors of the Public Health Laboratories were "grandfathered" into their positions since they were hired before certain federal clinical laboratory standards (i.e., "CLIA") were enacted in the early 1990's.

  These newer "CLIA" standards require additional academic degrees. Specifically, a director of a Public Health Laboratory must now (1) hold a doctorate in an approved area of laboratory science, (2) hold a Public Health Microbiologist certificate, and (3) be certified by one of six specified organizations.

  The $2.5 million (General Fund) would be used to fund a pre-doctoral program and contract with the University of California system (one program at UCLA and another at Berkeley). The major components of the program include the following:

- Support for doctoral students, plus a requirement that employed service in a Public Health Laboratory would be required for the state's support.
- Support for post-doctoral positions.
- Assistance to local public health laboratories to employ the graduates in paid positions so they can acquire the necessary public health laboratory experience.
- Support for an outreach program to encourage undergraduates in relevant sciences to apply to the doctoral programs.
- Require students upon completion of the program to

The DHS and Public Health Laboratory Directors, as well as other constituency groups, have been in contact with the University of California system regarding this proposal. All parties indicate that details are progressing well. Potential mechanisms for administering these local assistance funds include inter-agency agreements (such as with the UCs), and contracts directly with local health jurisdictions or another fiscal agent (such as a foundation).

- **State Support ($1.7 million).** Under this portion of the proposal, the DHS would **(1)** expend $200,000 to purchase molecular sequencing equipment and, **(2)** hire 13 new, permanent positions for the state's infectious diseases laboratories. Specifically, the positions are shown in the table below.

Classification of Position	Request	Purpose
Research Scientist III	1	Provide parasitology services
Research Scientist III	1	Provide mycology services
Public Health Microbiologist II	2	Provide immunoserology services
Subtotal Microbial Disease Lab	**4**	
Research Scientist III	2	Improving influenza diagnostics
Public Health Microbiologist	3	Improving influenza diagnostics
Public Health Microbiologist	3	Establish a molecular virology unit
Public Health Microbiologist	1	Maintaining quality control & assurance
Subtotal Viral & Rickettsial Disease	**9**	
TOTAL REQUEST	**13**	

Accurate laboratory services are essential to identifying infectious disease agents. The DHS is requesting these positions to improve the day-to-day demand for reference testing, to improve surge capacity, and to expand diagnostic testing (such as antiviral resistance testing, fungal diagnostics, serologic diagnostics, and more molecular techniques).

Overview of the DHS Infectious Disease Laboratories. Public Health Laboratories have a different mission than commercial laboratories. Many laboratory tests are not commercially viable, yet are necessary to maintain the public's health (as well as the individuals). **The DHS states that their infectious disease laboratories have expertise to perform over 8,000 different viral, Rickettsial, bacterial, fungal, and parasitic agents that can cause significant morbidity and mortality.**

The DHS infectious disease laboratories consist of the Microbial Diseases Laboratory (MDL) and the Viral and Rickettsial Diseases Laboratory (VRDL). **These laboratories provide the laboratory support, technical assistance, and research necessary for diagnosing, investigating, and controlling infectious diseases in California.** They provide diagnostic and epidemiologic laboratory support for 83 reportable diseases.

Examples of their activities include:

- Supporting epidemiologic investigations to control outbreaks of foodborne and waterborne diseases, determining sources of adulteration, and supporting product recall or quarantine by regulatory agencies;
- Supporting childhood vaccination programs regarding the prevalence and incidence of disease in children, targeted groups for vaccination, and emerging strains causing illness not covered by current vaccination regimens (e.g., whooping cough);
- Supporting active surveillance, control, and prevention of tuberculosis in immigrants entering California from Southeast Asia and the Pacific Rim by isolating these organisms from infected persons or travelers;
- Conducting surveillance of recreational camping and aquatic facilities for plague-carrying rodents;
- Confirming the presence or absence of bioterrorism agents (e.g., anthrax, plague, and smallpox);
- Investigating outbreaks of gastrointestinal illness;
- Performing HIV strain typing and viral load testing; and
- Conducting arbovirus surveillance, including West Nile virus.

Currently, the MDL has 36 General Fund positions, 12.5 federally funded positions and 7 contract positions. The DHS states that the federally funded and contract positions must work exclusively on the activities contained in their funded scope of work. Further, the DHS states that the existing General Fund positions are fully occupied with current activities.

The VRDL has 35 General Fund positions, 8 federally funded positions and about 40 contract positions. This laboratory is equally overextended and struggling to meet the testing needs in core areas, such as rabies, influenza, West Nile, respiratory outbreaks, hepatitis, HIV, vaccine-preventable diseases, and other items.

Background---Many Concerns with Scientific Capacity of Local and State Laboratories. Through a series of hearings and reports the Little Hoover Commission identified significant needs within California's public health system which require improvement, including the need to bolster the state's public laboratory network (i.e., 38 Public Laboratories and the state laboratories). Among many things the Commission noted that Californians should have access to timely review of serious pathogens, including for bio-safety level 4, and that specific strategies should be devised to ensure available scientific expertise. Further, the Commission noted that adequate laboratory capacity requires state-of-the-art facilities and equipment, highly trained staff, and surge capacity to respond to crisis.

Similar concerns were expressed in the Bureau of State Audits Report (Emergency Preparedness, August 2005) regarding improvements for Public Health Laboratories. They noted the need for scientific and research staff at the state level, and expressed concerns with developing needed professional expertise at the 38 Public Health Laboratories.

In addition, the Rand Corporation (Public Health Preparedness in California—Lessons Learned from Seven Health Jurisdictions, August 2004) has also identified the need for investment in our public health laboratory system.

Legislative Analyst's Office Recommendation--Approval. The LAO recommends approval of this request in recognition that California needs to bolster its scientific expertise and capabilities in regards to communicable diseases.

Subcommittee Staff Recommendation. Subcommittee staff concurs with the LAO recommendation. The need for these resources has been discussed for several years in various forums. California needs to strengthen its scientific expertise and capacity at both the local and state levels. This proposal moves in that direction.

Questions. The Subcommittee has requested the DHS to respond to the following questions.

1. DHS, Please describe how the $2.5 million program to attract and retain directors of Public Health Laboratories would operate.

2. DHS, Please provide a brief summation of why the requested 13 positions are necessary.

4. Expansion of Local and Statewide Communicable Disease Surveillance

Issue. The budget proposes **an increase of $1.3 million (General Fund) to support 4 new, permanent positions and contract funds. The primary function of this effort is to expand and maintain state and local capacity to conduct communicable disease surveillance.**

The $920,000 in contract funds would be used as follows:

- *Contract to University of California ($693,000).* The **DHS would contract with the UC system to obtain specialized services to conduct support, training, testing, customer service, interfacing, and quality control activities for statewide surveillance operations and initiatives.** *For example*, they would assist and coordinate information exchange between laboratories and public health agencies that will be connected via the various electronic laboratory reporting activities that are becoming available in a number of local health jurisdictions.
- *Other Specialized Consulting Services ($227,000).* The DHS states that these funds would be used to provide other specialized services. **Examples include security assessments/audits, graphic design for training and outreach materials, information management and modeling, and future feasibility studies.**

The requested positions include the following:

- *Research Scientist Supervisor I.* This position would serve as the manager of the unit and would provide expertise for developing and implementing public health information and surveillance strategies.
- *Research Scientist III (Epidemilogy/Biostatistics).* This position is responsible for designing and conducting scientific research to maximize the use of disease surveillance data. This position would have direct responsibility, in collaboration with the 61 local health jurisdictions, to analyze, interpret and disseminate disease surveillance information. This would include conceiving, directing and conducting epidemiologic studies and bio-statistical analyses of communicable diseases.
- *Associate Governmental Program Analyst.* This position would assist with the preparation of grant applications, contracts, and other requests for intramural and extramural funding. In addition they will monitor and track payments, prepare various reports and do other administrative functions.
- *Office Technician.* This position would provide clerical support, maintain inventory and records of equipment, prepare training and conference materials, and other related tasks.

Additional Background—Discussion of Surveillance Infrastructure. Surveillance is a core public health function that relies on various sources of information, data and knowledge to assess the health of the population, direct disease control and prevention efforts, and support policy development. **This often includes the use of various information technologies. The ability of the state and local policy-makers to**

respond to emerging threats to the public health is dependent upon the availability of accurate and complete information.

The DHS and local health jurisdictions have formed the "California Public Health Information Partnership (CalPHIP) which is a partnership specifically formed to coordinate disease reporting and surveillance improvements in the state, including web-based disease reporting for health care provides, laboratories, and local health jurisdictions. In addition, the DHS uses the CA Health Alert Network (to inform of potential problems/outbreaks) to maximize resource sharing between governments.

The DHS contends that though public health agencies in California have made progress toward developing and implementing systems for disease reporting and surveillance, there needs to be a more unified and coordinated approach.

Presently, the DHS uses about $4.8 million from existing federal bioterrorism grants to improve infectious disease epidemiology and investigation for bioterrorism agents. These funds support epidemiologist and research scientists and contracts working to improve disease recognition, investigation and control efforts in compliance plans approved by the federal agencies (federal CDC and federal HRSA).

Additional Comments. The Little Hoover Commission (June 2005), Bureau of State Audits Report (Emergency Preparedness, August 2005) and the Rand Report (August 2004) all have identified the need for improving the statewide communicable disease surveillance system.

Legislative Analyst's Office Recommendation--Approve. The LAO recommends approval of this proposal.

Subcommittee Staff Recommendation. It is recommended to approve as budgeted. The proposal is consistent with trying to build upon existing resources to better manage this complex field of communicable disease surveillance. It also addresses gaps in the existing system that have been identified through other analyses (i.e., the Little Hoover Report and the report prepared by Rand).

Questions. The Subcommittee has requested the DHS to respond to the following questions:

1. DHS, Please provide a brief summary of the request and why it is necessary.

5. Developing Workforce Capacity for Outbreak Response

Issue and Background. The DHS requests **an increase of $350,000 (General Fund) for consultant services to train existing public health field investigation staff (such as public health nurses and other public health professionals) that does not have emergency preparedness training.** According to the DHS, these funds will allow for a comprehensive field investigation training program to establish and **sustain a 100-person ready response team** for infectious diseases and bioterrorism emergencies.

Under this proposal, the DHS would contract with the CA Sexually Transmitted Disease/HIV Prevention Training Center (a national training center used for public health investigators and public health nurses). This training center would implement curriculum to train existing public health investigative staff to function as part of an emergency preparedness team. **This emergency preparedness training would include:**

- Locating and interviewing patients and their contacts;
- How to function in an incident command structure;
- Use of personal protective gear for various chemical agents;
- How to collect specimens according to criminal investigation standards;
- How to perform environmental assessments; and
- Effective implementation of legal orders and isolation.

There are many "frontline" public health professionals (about 400 people) working in state and local communicable disease programs, such as tracking and investigation of sexually transmitted diseases, TB and HIV. **These highly trained professionals have established extensive provider and community networks through their daily activities in case investigation, specimen collection, community forum participation, and provider visitations. As such, with the added skill sets through the consultant training, the expertise of these staff can be used in the event of a public health crisis.**

Legislative Analyst's Office Recommendation--Approve. The LAO recommends approval of this proposal.

Subcommittee Staff Recommendation. It is recommended **to modify the proposal by shifting the funding from General Fund support to federal fund support by using the newly provided federal funds for Pandemic Influenza.**

As noted under the background section of this agenda, the federal CDC has provided California with new funding of which we are presently authorized to spend 20 percent, or $1.3 million (federal funds). Further, the federal CDC has previously allowed the state to use funds for training purposes. **As such, there should be no concerns with this fund shift.**

6. Assuring Pandemic Influenza & Disease Outbreak Preparedness & Response

Issue. The DHS is requesting **an increase of $673,000 (General Fund) to fund 5 new, permanent positions to prepare for and respond to pandemic influenza.** These positions would conduct epidemiologic investigations of influenza and respiratory infectious disease outbreaks, and provide epidemiologic and statistical support to the department.

The requested positions and their intended purposes are as follows:

- *Immunization Branch (4 positions).* A total of four positions--Public Health Medical Officer, Nurse Consultant III, Research Scientist and Health Program Specialist—would be used to do the following key tasks:
    - Review state and national pandemic plans and develop standards for clinical activities that should be included in local pandemic influenza plans.
    - Communicate and coordinate with local, state and federal agencies and provide technical assistance.
    - Work with health care partners and other sources of influenza data to develop methodologies to evaluate influenza illness and vaccination coverage.
    - Research clinical care settings, including staffing, equipment and infrastructure to measure availability of surge capacity for an outbreak.
    - Develop standards of care for a clinical response to pandemic influenza, including antivirals, and vaccine prioritization strategies.
    - Conduct investigations of epidemiology and coordinate a statewide network of local and regional clinicians, epidemiologists and public and private laboratories to facilitate influenza activities.

- *Infectious Disease Branch (one position).* A Research Specialist III position would be used to provide epidemiologic and biostatistical support for the surveillance, prevention and control of influenza and respiratory disease outbreaks in coordination with the infectious disease laboratories.

The DHS states that these positions are necessary because they presently do not have the capacity to implement onsite epidemiologic investigation, or to provide the level of expertise required in the event of a pandemic influenza outbreak in California. They contend that these positions are needed to provide active planning and development of policies, procedures model emergency orders and risk communication strategies in order to prepare for any pandemic event.

Legislative Analyst's Office Recommendation--Deny. The LAO contends that the DHS could utilize existing positions, funded using federal bioterrorism funds, for these purposes.

Subcommittee Staff Recommendation. It is recommended to modify this proposal to provide **a total of three staff**—the Public Health Medical Officer, Nurse Consultant III, and Research Scientist positions for the Immunization Branch. **This would reduce the request by about $200,000 (General Fund).** Therefore the total appropriation would be about $473,000 (General Fund).

These positions would provide assistance to local health jurisdictions from an operational standpoint, by providing scientific and medical expertise. Currently, the DHS responds to flu and respiratory infection outbreaks on an ad hoc basis.

Questions. The Subcommittee has requested the DHS to respond to the following questions:

1. DHS, Please provide a brief summary of the proposal and how these positions are different than other positions being utilized within the department presently, or contained in other budget proposals.

7. Pandemic Influenza—Media Campaign

Issue. The budget proposes **a total increase of $14.3 million (General Fund) to develop and maintain a public education and media campaign for emergency preparedness and pandemic influenza.**

Of the total amount requested, $12.5 million (General Fund) would be used for the public information campaign and $1.3 million would be used for a hotline.

The remaining approximate $500,000 is for 5 new, permanent state positions. These include **(1)** Public Information Officer II, **(2)** Health Program Specialist II, **(3)** Health Education Consultant III, **(4)** Health Education Consultant II, and **(5)** Associate Governmental Program Analyst.

In addition, the proposal is seeking the Legislature's approval for a *sole-source contract.* The DHS contends that a sole-source contract is needed because a competitive request for application (RFA) or request for proposal (RFP) requires 6 months to one year to implement.

Specifically, the proposal includes funding for (1) outreach to other state agencies and private organizations to assure that they are addressing the impact of public health emergencies, **(2)** print, radio, and television advertisements, **(3)** a telephone hotline, **(4)** a contract with a public relations firm, and **(5)** state staff as noted.

Legislative Analyst's Office Recommendation—Deny. The LAO recommends denying the proposal because it is duplicative of other state efforts. For example, the Office of Emergency Services has a "Be Ready" campaign that was launched in April 2005. Further the LAO notes that both the DHS and CA Health and Human Services Agency have sufficient public relations staff that could supplement these efforts with free public service announcements.

Subcommittee Staff Recommendation. It is recommended to deny the proposal for the same reasons cited by the LAO. Further, a sole-source contract is not appropriate for this purpose. In addition, limited General Fund resources should not be used for this purpose. The Administration may want to consider using a portion of the one-time only federal funds which have recently become available (as discussed in the background section of this agenda) for this purpose.

Questions. The Subcommittee has requested the DHS to respond to the following questions.

1. DHS, Please provide a brief summary of the request.

8. Health Care and Community Infection Control Program *(See Hand Out)*

Issue: The budget proposes **an increase of $1.4 million (General Fund) and 10 new, permanent positions to develop and maintain an ongoing program for the surveillance, laboratory testing, prevention and control of infections in health care facilities and certain community-settings.** Specifically, this proposed program is intended to address hospital and healthcare-associated infections and community infections for which infection control measures are the primary method of control.

In addition, the DHS is proposing trailer bill legislation to make healthcare-associated infections reportable by health care facilities licensed under Section 1250 (a), (b), (c), (f) and (k) of the Health and Safety Code. These facilities include General Acute Care Hospitals, Acute Psychiatric Hospitals, Skilled Nursing Facilities, and specialty hospitals.

The DHS states that the proposed 10 new, permanent positions would be used as follows:

- *Infectious Disease Branch (5 positions).* A total of five positions—two Public Health Medical Officer III's, Nurse Consultant III, Research Scientist III, and Health Program Specialist—would be used to conduct the following key functions:
    - Provide guidance on interpretation of infection surveillance and prevention recommendations issued by the federal Centers for Disease Control (CDC) and other organizations.
    - Develop training and education programs for health care facility infection surveillance and prevention professionals new to the profession.
    - Participate in developing educational programs on infection surveillance and prevention for local health jurisdictions and the general public.
    - Provide consultation and assistance to other state agencies in the development and implementation of infection surveillance and prevention guidelines.
    - Provide educational materials, on-line training programs and information on website.

- *Microbial Diseases Laboratory.* A total of five positions—two Research Scientist III's, two Public Health Microbiologist II's, and a Public Health Laboratory Technician would be used to conduct the following key functions:
    - Assist in the investigation and follow-up of clusters and outbreaks of health care facility associated infections.
    - Provide sufficient laboratory efforts to support health care facilities and local health jurisdictions with pathogen identification, molecular epidemiology and anti-microbial susceptibility testing for the investigation of outbreaks.
    - Oversee the development and evaluation of new tests and testing technologies for the rapid detection and strain typing of hospital care associated infections.

- Performs scientific research studies of moderate scope and complexity for the detection of hospital care associated infections.
- Create, maintain and utilize databases relevant to microbial strain typing patterns.

Administration's Proposed Trailer Bill Language (See Hand Out). The Administration is proposing trailer bill language to add a new section to Health and Safety Code which requires health care facilities, as specified, to provide data on a quarterly basis according to federal CDC guidelines. This reporting would commence as of January 1, 2008. The DHS would promulgate regulations to implement this reporting by July 1, 2007. Though the DHS would provide an annual report, patient outcome data specific to a reporting licensed facility would not be made public.

This language is significantly different than legislation—SB 739 (Speier)—which is in the Assembly. SB 739 was last amended as of August 30, 2005.

Background—Concern with Infections in Health Care Settings. According to the DHS, California's 450 hospitals account for an estimated 300,000 infections, 13,500 deaths, and $675 million in excess health care costs annually. Many more infections occur in California's 1,500 nursing homes and long-term care facilities, 800 Intermediate Care Facilities, 600 ambulatory surgical centers, and 350 dialysis centers.

Community-acquired antibiotic-resistant Staphylococcus aureus emerged in California about 5 years ago and it is already the predominant cause of skin and soft tissue infections as well as an invasive disease in many communities. This pathogen is responsible for major outbreaks of infection in jails, prisons, and athletic teams, and is becoming a problem in various health care facilities.

The DHS notes that state guidelines for infection control and prevention are needed for each of these settings, since there are no national guidelines or standards. DHS has established a Health Care Associated Infections Advisory Working Group to develop recommendations for health care facilities on preventing and controlling infections.

The DHS states that two positions are used to address infection control issues (a Public Health Medical Officer III located in the Division of Communicable Disease and a Nurse Consultant located in Licensing and Certification). **Both of these positions are presently funded by the Licensing and Certification Division of the DHS. No resources currently exist to provide on-going training and technical assistance to L&C surveyors to improve their ability to identify and investigate infection control practice problems. Further according to the DHS, there has been no ability to follow-up to assess how a health facility has corrected a problem that may have caused an outbreak and whether they can sustain improvement in infection control to prevent further outbreaks.**

DHS states that no data on health care associated infections is currently required to be collected or reported in California. Legislation mandating such reporting has been passed in 6 states in the past year.

Background—Existing Legislation in Assembly. Senate Bill 739 (Speier), as amended on August 30, 2005, addresses many of the policy issues regarding health care associated infections. This legislation is presently in the Assembly.

Legislative Analyst's Office Recommendation—Use Fees in Lieu of General Fund. The LAO notes that this new DHS program would directly benefit health care facilities since it would reduce the number of costly infections. Therefore, they believe imposing fees on these facilities to support this proposal is a reasonable approach.

Subcommittee Staff Recommendation. It is recommended to deny this proposal without prejudice and direct the Administration to craft legislation through the policy committee process. This proposal would commence an entirely new program and requires considerable policy debate on reporting requirements, appropriateness of fees and discussions regarding program objectives and outcomes. Further, the Administration can work with Senator Speier regarding her legislation to see if a compromise is achievable.

Questions. The Subcommittee has requested the DHS to respond to the following questions.

1. DHS, Please briefly explain the budget proposal and the proposed trailer bill legislation.

9. Preparedness for Chemical and Radiological Disasters and Terrorist Attacks

Issue. The budget proposes **a total increase of $4.2 million (General Fund) to support 15 new, permanent positions, hire consultant staff and purchase equipment to prepare for chemical and radiological disasters and attacks on (1) the environment, (2) food, and (3) water.** The proposed equipment costs are $880,000 and the consultant expenditures are $1.3 million. Both of these costs are contained within the $4.2 million amount.

According to the LAO, the funding and positions can be *generally* segmented into the following areas:

- *Environment.* A total of $1.2 million (General Fund) and 4 positions (Research Scientist I, Research Scientist II, Research Scientist III, and a Health Education Consultant III) are identified for this function.
- *Food.* A total of $1.6 million (General Fund) and 6 positions (two Associate Health Physicists and four Research Scientist IV's)
- *Water.* A total of $1.4 million (General Fund) and 5 positions (all Associate Sanitary Engineers)

According to the DHS, these resources would be used to do the following key functions:

- Develop plans and support training for public health responses to chemical and radiological contamination resulting from disasters and terrorist attacks;
- Develop food and water protection plans against intentional contamination with chemical and radiological agents;
- Provide training to local jurisdictions and the food industry; and
- Enhance laboratory capability to rapidly and accurately identify chemicals and radiological agents contaminating food, water and the environment in disasters and terrorist attacks.

According to the DHS, funding for chemical and radiological terrorism preparedness has focused traditionally on first responders. **The DHS notes that federal funds received from the federal Centers for Disease Control and other agencies have *not* provided funding to cover planning, preparing, training, and exercising in response to chemical or radiological terrorism.** As such, the DHS believes that resources are needed to establish minimum capabilities for preparedness and response to chemical or radiological attacks.

Additional Background—Other Funding Sources Availability. As noted by the LAO, the DHS already inspects, surveys and oversees food processors and manufacturers for food contaminants on a fee-supported basis. In addition, Proposition 50 bond funds, as well as other special funds and federal funds are used to protect and monitor water facilities.

Legislative Analyst's Office Recommendation. The LAO makes the following recommendation regarding the three aspects of this proposal:

- *Environmental ($1.2 million and 4 positions).* The LAO recommends approval of this component as proposed.

- *Food ($1.6 million General Fund and 6 positions*). The LAO recommends shifting these expenditures from General Fund support to fee supported.

- *Water* ($1.4 million General Fund and 5 positions). The LAO recommends denying this proposal because water security activities likely are eligible for funding from the federal bioterrorism grant provided to the state by the federal CDC, as well as Proposition 50 bond funds.

Subcommittee Staff Recommendation. It is recommended to adopt the LAO recommendation. **These positions would provide an initial framework to commence more comprehensive work in this area.**

Questions. The Subcommittee has requested the DHS and LAO to respond to the following questions.

1. DHS, Please provide a brief summary of the request.

2. LAO, Please present your recommendation.

LAST PAGE OF AGENDA.